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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/695,516 Confirmation No.: 8073  
Applicant : John D. WAGSTAFF et al.  
Filed : 29 October 2003  
TC/A.U. : 1654  
Examiner : Jennifer I. HARLE  
  
Attorney Docket No. : 2314-271  
Customer No. : 6449

Director of the United States Patent  
and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO RESTRICTION REQUIREMENT**

Dear Sir:

In the Office Action mailed 13 March 2006, the Examiner required restriction between four Groups, each directed to the treatment of pain, and an election of species for the active agent. In response to this Office Action, Applicants elect Group I, claims 15-16 and 2-3 for examination. This election is made with traverse. With respect to the species, Applicants elect the peptide of SEQ ID NO:1. This election is also made with traverse. Claims 1-3, 8-14 and 21-26 read on the election of Group I and SEQ ID NO:1. If this requirement further includes an election of a glycan, the glycan of claim 12 is elected. This election is made with traverse. Claims 1-3, 8-12, 14, 21-25 read on the election of Group I, SEQ ID NO:1 and the glycan Gal( $\beta$ 1-3)GalNAc( $\alpha$ 1-).

Applicants note that there are two criteria for a proper requirement for restriction between patentably distinct inventions: 1) The inventions must be independent or distinct as claimed; and 2) There must be a serious burden on the Examiner if restriction is not required. See MPEP § 803. Examiners must provide reasons and/or examples to support conclusions. For purposes of the initial requirement, a serious burden on the Examiner may be *prima facie* shown if the Examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field

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of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria are set forth in MPEP § 803.02. See MPEP § 803. If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the Examiner will not require restriction. See MPEP § 803.02.

Even if the groups and peptide species may be distinct, which Applicants do not concede, distinctness alone is not enough to require a restriction as stated in the MPEP, as discussed above. There must also be a serious burden upon the Examiner. In the absence of such a burden, the examiner must examine all of the claims (or in this case, it is urged that all of the peptide claims should be examined). It is urged that the burden of examining all of the types of pain in the claims of the present application is not a serious one, and that the burden of examining all of the types of pain claims is only slightly greater than examining one of the groups of claims. In this connection, Applicants note that the classification for each group is identical, i.e., class 514, subclass 13. Thus, a single field of search is all that is required in order to search for all of the types of pain that are set forth in the claims, and this search does not impose an undue burden on the Examiner. In addition, it is submitted that keyword searching using the term pain, as it appears in the linking claims, will identify prior art that relates to each and all of the types of pain set forth in the claims. Thus, a single keyword search is all that may be required, and this search does not impose an undue burden on the Examiner. Finally, the Examiner states “[P]rior art which teaches the one method **may be** novel or unobvious for another method.” (emphasis added) This statement by the Examiner is inconsistent with her assertion that the methods for treating the different types of pain are patentably distinct, and is consistent with Applicants position that the restriction is not proper.

Similar arguments also apply to the peptide. In this connection, Applicants further submit that a computer search of the peptide of SEQ ID NO:1 would identify all peptides related to this

peptide that is encompassed by the claims, including CGX-1160 and CGX-1063. Thus, Applicants submit that searching all of the peptides set forth in the claims would not impose an undue burden on the Examiner.

With respect to the peptides, the examination entails various aspects. (Although not specifically set forth below, similar comments can be made with respect to the methods of treatment.) First is a decision concerning utility under 35 U.S.C. §101. Although each peptide species being claimed is distinct, they are all related in their structure and biological activity. Consequently, a decision concerning utility will be identical for all of the species, and there is no added burden of examining all of the species as compared to examining only a single species.

The second aspect of examination is whether the provisions of the various paragraphs of 35 U.S.C. § 112 have been met. In general, and in this case, this means reviewing the application and claims for compliance with the provisions of paragraphs 1 and 2 of § 112. As for the enablement aspect as found in paragraph 1 of § 112, all of the peptides are related in their structure and biological activity. Since no basis for distinguishing between the enablement of one species vs. another species has been set forth, it is presumed that all of the listed peptides will be treated equally. Again, this means that only a single decision needs to be made concerning all of the peptides. Therefore, this aspect of the examination will not be a serious burden if all peptides are examined, vs. only one of the peptides.

Concerning paragraph 2 of § 112, this involves the wording of the claims. The wording of the claims in each group of claims is identical except for the specified peptide. Consequently, any objections to the language of the claims for one Group of claims is equally applicable to the other Groups of claims. Therefore there is no increase in the burden concerning 35 U.S.C. § 112, second paragraph, if all peptide claims are examined.

The third aspect of examination is a review of prior art to determine whether the claims are anticipated or obvious. There are two aspects of such a search. A first aspect is a review of the prior art literature and patents. The literature to be reviewed will be identical for all of the peptides. All

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of the claimed peptides have similar, though not identical, structures and all are claimed to have the same utility. The Examiner has not stated that a search of the scientific literature will be any different for one peptide than for any other peptide. Consequently, the search of the patent literature will clearly be the same for all of the peptides. Because the search of the scientific literature and patent literature will be identical for all of the peptides, there is no added burden concerning this aspect if all of the peptides are examined. Furthermore, the search will probably entail a computer search based on the peptide sequences in the sequence listing. It is believed that such a search would identify prior art directed to the claimed peptides or peptides having the specified substitutions. In addition, Applicants submit that a search of the peptide will also identify its propeptide, thus there is no additional burden in searching the propeptide. Furthermore, Applicants submit that a search of the peptide will also identify any derivatives or analogs, such as set forth in claims 3-9.

Consequently, it is submitted that the only reason for restriction is that the peptides are distinct from each other. But as explicitly stated in MPEP § 803, the inventions must be distinct and there must be a serious burden on the examiner. MPEP § 803.02 states that if a search and examination of an entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. As urged above, it is asserted that examination of all of the peptides claims will not impose a serious burden.

In view of the above arguments, it is requested that the restriction requirement imposed in the Office Action mailed 13 March 2006 with respect to different types of pain and with respect to